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10/15/2000
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Richard F. Staack, Ph.D.
Senior Scientist
Cognis Corporation
5325 South Ninth Avenue
La Grange, Illinois 60525-3602

Dear Dr. Staack:

This is in response to your letter of October 4, 2000 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)). Your submission states that Cognis Corporation is making the following claims, among others, for the product "LIPOEC®:"

- "A safe blood-sugar balancer;"
- "...helps maintain insulin function and promotes glucose metabolism...;"
- "Blood-sugar balancer."
- "...effect on insulin function and glucose (blood sugar) ..."
- "...help maintain desirable "insulin sensitivity", and indicator of efficient insulin function."

21 U.S.C. 343(r)(6) makes clear that a statement included in labeling under the authority of that section may not claim to diagnose, mitigate, treat, cure, or prevent a specific disease or class of diseases. The statements that you are making for this product suggest that it is intended to treat, prevent, or mitigate a disease, namely diabetes. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that this product is intended for use as a drug within the meaning of 21 U.S.C. 321(g)(1)(B), and that it is subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

975-0163

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Please contact us if we may be of further assistance.

Sincerely,

John B. Foret
Director
Division of Compliance and Enforcement
Office of Nutritional Products, Labeling,
and Dietary Supplements
Center for Food Safety
and Applied Nutrition

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Copies:

FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300
FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200
FDA, Chicago District Office, Office of Compliance, HFR-MW140

cc:

HFA-224 (w/incoming)
HFA-305 (docket 97S-0163)
HFS-22 (CCO)
HFS-800 (r/f, file)
HFS-811 (file)
HFD-40 (Behrman)
HFD-310
HFD-314 (Aronson)
HFS-605 ..
HFY-228 (Benz)
GCF-1 (Nickerson, Dorsey)
f/t:HFS-811:afp:10/19/00:72825.disc1



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October 4, 2000

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 C Street SW
Washington, DC 20204

To the Food and Drug Administration:

Pursuant to section 403(r)(6) for the Federal Food, Drug, and Cosmetic Act (FDC Act), 21.U.S.C. § 343 (r)(6), we hereby notify the FDA that Cognis Corporation has included the following statements in labeling for a dietary ingredient that it manufactures and markets for use in dietary supplement products.

The following information is provided:

1. The name and address of the manufacturer and distributor of the dietary ingredient is as follows: Cognis Corporation, 5325 South 9th Avenue, LaGrange, IL 60525-3602.

2. The text of the labeling statements is as follows:

“A safe blood-sugar balancer”

“A proven cell protector”

“In humans and other mammals, alpha-lipoic acid serves as a component of several key enzyme complexes, including pyruvate dehydrogenase and alpha-ketoglutarate dehydrogenase. These enzymes are required in the “Krebs cycle,” which breaks down carbohydrate molecules and converts them to energy.”

✓ “At high doses, alpha-lipoic acid helps maintain insulin function and promotes glucose metabolism, and it also helps protect the liver and other tissues in certain populations.”

“...alpha-lipoic acid is routinely converted in the body to dihydrolipoic acid, another highly efficient antioxidant.”

“Together, these two forms of alpha-lipoic acid neutralize a broad variety of free radicals.”

... acid helps recycle and replenish vitamins E and C, glutathione, and coenzyme Q10—all-important antioxidants—enabling the body to extend their biological lifespans.”

“...alpha-lipoic acid also helps the body produce more of the powerful antioxidant, glutathione.”

“... research has also shown that antioxidants are synergistic and, as a team, have greater free-radical quenching properties than individual antioxidants.”

✓ “Blood-sugar balancer”

“In Germany and other European nations where alpha-lipoic acid is prescribed, it has a long history of use helping people in certain populations maintain normal nerve function.”

✓ “During the 1990s, researchers learned that alpha-lipoic acid exerts a positive effect on insulin function and glucose (blood sugar) utilization in those populations.”

✓ “Alpha-lipoic acid may help maintain desirable “insulin sensitivity”, an indicator of efficient insulin function.”

“Protector of Cell Integrity.”

“Through a variety of actions, including its antioxidant properties, alpha-lipoic acid can help maintain cell integrity in the face of biological threats.”

“Studies and clinical experiences have shown that alpha-lipoic acid can help preserve normal liver function when the body is exposed to certain toxins.”

“...other research has found that alpha-lipoic acid helps protect nerve function, such as by normalizing the transmission of nerve signals in the body.”